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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,118	ERITJA ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-6, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 1, classified in class 435, subclass 5.

II. Claims 7-9, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 2, classified in class 435, subclass 5.

III. Claims 10-12, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 3, classified in class 435, subclass 5.

IV. Claims 13-15, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 4, classified in class 435, subclass 5.

V. Claims 16-18, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 5, classified in class 435, subclass 5.

VI. Claims 19-21, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 6, classified in class 435, subclass 5.

VII. Claims 22-24, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 7, classified in class 435, subclass 5.

VIII. Claims 25-27, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 8, classified in class 435, subclass 5.

IX. Claims 28-30, drawn to a method for testing a sample for the presence of at least one strain of West Nile Virus, wherein a target sequence comprises SEQ ID NO: 9, classified in class 435, subclass 5.

X. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 1, classified in class 536, subclass 23.1.

XI. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 2, classified in class 536, subclass 23.1.

XII. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 3, classified in class 536, subclass 23.1.

XIII. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 4, classified in class 536, subclass 23.1.

XIV. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 5, classified in class 536, subclass 23.1.

XV. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 6, classified in class 536, subclass 23.1.

XVI. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 7, classified in class 536, subclass 23.1.

XVII. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 8, classified in class 536, subclass 23.1.

XVIII. Claim 39 (in part), drawn to a nucleic acid probe for detecting a target sequence of SEQ ID NO: 9, classified in class 536, subclass 23.1.

XIX. Claim 40, drawn to a method for treating a patient having a West Nile Virus, classified in class 435, subclass 5.

XX. Claim 46, drawn to a method for inhibiting reproduction of the West Nile Virus, classified in class 435, subclass 5.

Claims 1-3, 31-34 and 41-45 link(s) inventions I, II, III, IV, V, VI, VII, VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-34, and 41-45. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 35-38 link(s) inventions X, XI, XII, XIII, XIV, XV, XVI, XVII, and XVIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 35-38. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I, II, III, IV, V, VI, VII, VIII, IX) and (X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method for testing a sample for the presence of at least one strain of West Nile Virus can be practiced with another materially different product. The presence of West Nile Virus in a sample can be detected using an immunoassay. Literature search regarding the method of testing a sample for the presence of West Nile Virus will not necessarily reveal the literature regarding the nucleic acid probe. Additionally searching all nucleic acid sequences together would pose a serious search burden on the Office. The sequences are distinct structurally and functionally. Searching one nucleic acid sequence would not reveal the literature regarding other nucleic acid sequences.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions (I, II, III, IV, V, VI, VII, VIII, IX), XIX, and XX are directed to related method for testing a sample for the presence of at least one strain of West Nile Virus, a method

for treating a patient having a West Nile Virus, and a method for inhibiting reproduction of the West Nile Virus. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related methods have different mode of operation, such as the method of testing the sample for the presence of at least one strain of West Nile Virus is performed *in vitro*, the method for treating a patient having a West Nile Virus involves administering a therapeutic composition to the patient, and a method for inhibiting reproduction of the West Nile Virus occurs *in vivo*.

Literature search regarding the method of one group will not necessarily reveal the literature regarding another group.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions (X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII) and (XIX, XX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acid probe can be used in a materially different process other than using it in a method for

inhibiting reproduction of the West Nile Virus. The nucleic acid probe can be used in the method for detection of the West Nile Virus.

Inventions XIX and XX are directed to related method of treating a patient having a West Nile Virus and a method of inhibiting reproduction of the virus. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the distinct methods are not obvious variants. The method of treating a patient comprising administering a therapeutic amount of a composition capable of binding the RNA of the West Nile Virus is different from a method for inhibiting reproduction of the West Nile Virus that can be done in the in vitro setting.

Because the inventions are distinct for the reasons given above and the literature search required for one group is not co-extensive with any other group, and therefore presents a serious burden of search, restriction for examination as indicated is proper.

Should either of groups XIX or XX be elected a further election of species is required.

Claims 40 and 46 are generic to the following disclosed patentably distinct species: SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9. The species are independent or distinct because they

represent nucleic acid sequences that are different structurally and functionally. It would be an undue burden for the Office to search all nucleic acid sequences together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

May 18, 2006

BRUCE R. CAMPELL, PH.D
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